

Appln No.: 09/581,058
Amendment Dated: November 6, 2003
Reply to Office Action of December 3, 2002

REMARKS/ARGUMENTS

This amendment is filed in lieu of an Appeal Brief, and accompanies an Request for Continuing Examination. Reconsideration and further examination are respectfully requested.

Applicants request an extension of time sufficient to make this paper timely, and enclose the appropriate fee. The Commissioner is authorized to charge any additional fees or credit any overpayments to Deposit Account No. 15-0610.

In the Office of December 3, 2002, Examiner Thompson asserted that claims 22-32 under 35 USC § 112, first paragraph as introducing new matter, and to the substitute specification as introducing new matter. In the office action, it was stated that the terms "connecting device" "system comprising a ... transfer device and a connecting device" and "methods" were new matter, and also the weakened zone of claim 15. In the Advisory Action, Examiner Ghafoorian does not refer to the connecting device, but has added additional assertions of new matter. Applicants respectfully disagree with these rejections.

Applicants respectfully point out that the standard for assessing whether a change in the specification or claims is "new matter" or whether it is supported by the original disclosure is not whether the exact words later added are in the original application. The standard is whether a person of ordinary skill in the art would understand that the applicant had invented that which is later claimed. In this case, the original disclosure, as reflected in published PCT application WO99/34754, plainly supports the amendments.

With respect to the connecting device, the response filed April 7, 2003 reproduced claims 22-32 showing the reference numerals in the figures which correspond to each part as recited, and which provide the basis for the textual description of the various parts. Furthermore, original claims 1, 2 and 9-12 were directed to portions of the connection means.

With respect to the "system" claim 33, Applicants have amended this claim to refer to a combination. Since the claims refers to the percutaneous bone anchoring device (as described in claim 13) and the connecting device (as described in claim 22) and since the application clearly contemplates the use of these two parts of the device in combination (for example as depicted in Fig. 7), it is not understood how this could be new matter.

With respect to method claim 34, this is a method of using the devices disclosed in the application. Figs. 1 and 13 show placement of invention in soft tissue and bone, and the fact that the device would be used, and thus that the method for its use had been invented, would plainly be understood. Note also that the description of the figures starting on Page 9, line 30 is in terms of method steps, (is anchored, is placed ... by boring and lowering etc.) The specific method

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steps recited in the claim are:

placing an implanted unit into a subject through a bore hole that has been made through soft tissue and bone of the subject;

The original application, at Page 1, lines 6-11 states that there is a need for "transferring electrical information and/or electric energy to an inner subcutaneous permanently implanted unit" and indicates that the device is used (i.e., it provides the means) to permit an outer electric unit to be connected to an inner implanted subcutaneous unit. In addition, an implanted unit is shown in Fig. 13 (inner unit) as into a subject through a bore hole/ bone channel that has been made through soft tissue and bone of the subject. See also page 5, lines 26-27; page 9, lines 30-31; page 10, lines 1-5.

connecting the implanted unit through the first connection unit of the connecting device to the middle connecting unit;

Fig. 2 shows the cable from the inner unit passing through the connection unit to connect with the middle connecting unit. See also Page 7, line 20-Page 8, lines 8.

placing the percutaneous bone-anchored transferring device over the first connection unit and middle connecting unit and into the bore hole such that the bottom part of the percutaneous bone-anchored transferring device is inside the bore hole and the radial arms are resting on the outer surface of the bone with the tissue temporarily moved to a side;

This placement of the transfer device in this position is shown in Figs. 1 and 13.

fastening the radial arms into the bone;

Fastening is done by screws 4 in Fig. 1, and is described on Page 10, line 1.

connecting the outer contact unit to the middle connecting unit;

Connection of the outer contact unit {41} to the middle connecting unit {31} is shown in in Fig. 7 and is referenced in original Claim 9 and on Page 11, lines 13-15.

connecting the outer contact unit to an outer device; and

Connection of the outer contact unit {41} to an outer device is shown in Fig. 13 (outer unit) and is described on Page 1, lines 9-15.

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activating the outer device to transfer electrical signals or energy to and/or from the implanted unit or to administer a chemical through the implanted unit or to evacuate or air internal cavities through the implanted unit.

Thus final step activates the device, and is merely closure on the stated and supported method. See also original claims 1, 3 and 10; page 1, lines 6-7 and 13-17; page 5; lines 16-24; page 8, lines 10-29; page 12, lines 18-24.

Thus, the basis for the new matter rejection of claim 34 is not understood. Claims 35 and 36 contain similar limitations that are equally based on the original specification as was fully explained in the response filed April 7, 2003.

Examiner Ghafoorian, in the Advisory Action, states that reference numeral 3 in the old specification referred to an "electrical connection" at Page 9, line 31 and Page 10, line 6. The new specification was filed in part to rationalize clerical errors including the one relied upon by the Examiner for a lack of support. It is note that in Fig. 1, numeral 3 refers to a transferring device (see abstract) and on page 10, line 7 as a connection. The reference numeral 3 actually in Fig. 1 refers to the entire assembly (the system or combination as now claimed) and the amendments to the specification merely reflect a more consistent description and are not new matter.

With respect to the "weakened zone", the Examiner's attention is directed to original claim 7 which recited that "the upper part (14) of the body (11) is provided with a weakened zone," and the original specification, Page 10, lines 13-14, which noted that "in the upper part 14 the transferring part 11 is thinned to allow deformation if a large load should occur on the transferring part 11." The reference to the weakened zone in the text, merely connects the original language of claim 7 to the original language of the specification in a manner that would be understood by a person skilled in the art.

For these reasons, Applicants submit that the new matter rejection should be withdrawn.

On the merits, Examiner Ghafoorian kindly provided an explanation of the basis on which certain elements of claims 13- 21 were assertedly met by the Ray patent. Among these was an assertion that the circular flange 13 of Ray meets the limitation of "radial arms" in the claims. Given the plurality of arms implicit in this statement, it is not clear how this position is supported in the reference. Nevertheless, Applicants have amended the claims to refer to a "plurality of separate radial arms" to avoid any possibility that the claims would read on a continuous ring as shown in Ray. This amendment is supported by the ordinary meaning of the term "arms" and in Fig. 4.

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For these reasons, this application is now considered to be in condition for allowance and such action is earnestly solicited.

Respectfully Submitted,



Marina T. Larson, Ph.D
Attorney/Agent for Applicant(s)
Reg. No. 32038

(970) 468 6600